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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,683	11/04/2003	Robert C. Brunham	1038-1273 MIS:ah	2991

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EXAMINER	
PORTNER, VIRGINIA ALLEN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,683	BRUNHAM ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,21,22 and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,21-22,24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 19, 21-22, 24-28 are pending. All claims recite a new combination of claim limitations through amendment of independent claim 19.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Withdrawn

1. ***Claim Rejections - 35 USC § 102*** Claims 19, 21-22, 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Murdin et al (US Pat. 6,693,087, effective filing date August 20, 1998) in light of WO92/11361.
2. Claims 19, 21-22, 24-28 under 35 U.S.C. 102(e) as being anticipated by Murdin et al (US Pat. 6,686,339, effective filing date August 20, 1998) in light of WO92/11361,
3. Claims 19, 24, 25, 27-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Darji et al (1997) in view of Brey et al (US Pat. 5,919,663, filing date Jan. 30, 1995) in light of the amendment of claim 19 to recite the term "MOMP" which is not disclosed in either of Darji et al or Brey et al.

New Combination of Claim Limitations/ New Grounds of Rejection
Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 19, 21-22, 24-28 are rejected under 35 U.S.C. 103(a) as being obvious over Murdin et al (US Pat. 6,686,339, effective filing date August 20, 1998) in light of WO92/11361..

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Instant claim 19: Murdin et al teach, suggest and provide guidance for the formulation of instantly claimed invention (see Murdin et al: "In the C. pneumoniae genome, open reading frames (ORFs) encoding chlamydial polypeptides have been identified. These polypeptides include polypeptides permanently found in the *bacterial membrane structure*, polypeptides that are present in the external vicinity of the bacterial membrane, include polypeptides permanently found in the inclusion membrane structure, polypeptides that are present in the external vicinity of the inclusion membrane, and polypeptides that are released into the cytoplasm of the infected cell. These polypeptides can be used in vaccination methods for preventing and treating Chlamydia infection. ")

directed to an attenuated strain of an auxotrophic bacterium, that is an attenuated Salmonella typhimurium strain (the vaccine vector (see col. 4, lines 36-37; col. 11,67) in an immunogenic composition is disclosed to be an attenuated Salmonella typhimurium strain genetically engineered for recombinant expression of heterologous antigens, used an oral vaccine (see col. 13, lines 49-55), and the attenuation is defined in light of WO92/11361 which shows Salmonella typhimurium auxotrophic attenuated strains (see WO92', page 4, paragraphs 3-4), the attenuated Salmonella comprising a heterologous nucleic acid encoding at least one membrane protein of Chalmydia (see col. 5, lines 32-42 and col. 12, lines 33-35), and teaches MOMP proteins are able to not only induce cross strain antibody binding, but also are produce neutralization of infectivity (see col. 8, lines 15-21).

Instant claim 20: wherein the nucleic acid coding sequence is obtained from Chlamydia pneumoniae (see col. 12, line 21).

Instant claim 21: wherein the nucleic acid coding sequence is obtained from Chlamydia trachomatis (see col. 12, line 20).

Instant claim 24: the nucleic acid is operatively coupled to a nucleic acid for expression of the membrane protein, the nucleic acid being a cytomegalovirus promoter (see col. 10, lines 44-59, col. 14, lines 25-26; col. 12, 27-48).

Instant claim 25: the vector is a plasmid vector (see col. 13, lines 54-56; col. 11, lines 39-40; col. 12, 1).

Instant claims 27-28: wherein the auxotrophic bacterium harbours a vector (see col. 4, lines 35-57 "a recombinant host system and related expression cassettes, vectors and transformed cells, ie live vaccine vector Salmonella typhimurium), formulated into a delivery vehicle.

Instant claim 26: Murdin et al teaches and suggests the formulation of vaccine vectors that can express one or several polypeptides and at least one additional Chlamydia antigen to include the nucleic acid that encodes MOMP (to include the nucleic acid that encodes MOMP (see col. 3, lines 62-67 and col. 4, lines 1-12(" Serovars of C. trachomatis are defined on the basis of antigenic variation in MOMP, but published C. pneumoniae MOMP gene sequences show no variation between several diverse isolates of the organism (refs. 34 to 36). The gene encoding a 76kDa antigen has been cloned from a single strain of C. pneumoniae and the sequence published (ref. 48).")),

but differs from the instantly claimed invention by failing to show the MOMP nucleic acid sequence inserted into the vaccine vector system that comprises an attenuated Salmonella typhimurium host cell.

6. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to formulate the attenuated Salmonella typhimurium vaccine vector that

comprises a plasmid that encodes a Chlamydia membrane protein, to further encode and express at least one additional Chlamydia antigen (see Murdin et al col. 12, lines 33-35) , specifically MOMP protein under the control of a cytomegalovirus promoter as taught by Murdin et al because Murdin et al teaches, provides guidance and suggests the formulation of vaccine vectors that are able to express the MOMP nucleic in the cells of a host for the induction of antibodies which will bind to Chlamydia because the MOMP nucleic acid has been previously cloned and expressed and vaccine vector system is one that is able to express one or several nucleic acids obtained Chlamydia (see col. 1, lines 15-16) .

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of obtaining the vaccine vector system which is able to be recombinantly express MOMP protein and to induce a neutralizing protective immune response directed against MOMP in the cells of a host, because Murdin et al teach the MOMP proteins have been successfully cloned and expressed and the MOMP proteins are immunogenic and induce neutralizing antibodies which assist in prevention of infection (see col. 8, lines 17-20) and Murdin et al teach, suggest and provide guidance for the incorporation of Chlamydial nucleic acids (at least one additional Chlamydial coding sequence) into the described vaccine vector systems (see claims and entire document), wherein the expressed Chalmydial proteins are able to induce a protective immune response (see col. 3, lines 62-67 and col. 4, lines 1-12). Murdin et al obviate the instantly claimed invention as now claimed.

7. Claims 19, 21-22, 24-28 are rejected under 35 U.S.C. 103(a) as being obvious over Murdin et al (US Pat. 6,693,087, effective filing date August 20, 1998) in light of WO92/11361..

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Instant claim 19: Murdin et al teach, suggest and provide guidance for the formulation of instantly claimed invention (see Murdin et al: "In the C. pneumoniae genome, open reading frames (ORFs) encoding chlamydial polypeptides have been identified. These polypeptides include polypeptides permanently found in the *bacterial membrane structure*, polypeptides that are present in the external vicinity of the bacterial membrane, include polypeptides permanently found in the inclusion membrane structure, polypeptides that are present in the external vicinity of the inclusion membrane, and polypeptides that are released into the cytoplasm of the infected cell. These polypeptides can be used in vaccination methods for preventing and treating Chlamydia infection. " (col. 5, lines 29-40)

directed to an attenuated strain of an auxotrophic bacterium, that is an attenuated Salmonella typhimurium strain (the vaccine vector (see col. 4, lines 30-37; col. 11, line 31-32) in an immunogenic composition is disclosed to be an attenuated Salmonella typhimurium strain genetically engineered for recombinant expression of heterologous antigens, used an oral vaccine (see col. 13, lines 50-54), and the attenuation is defined in light of WO92/11361 which shows Salmonella typhimurium auxotrophic attenuated strains (see WO92', page 4, paragraphs 3-4), the attenuated Salmonella comprising a heterologous nucleic acid encoding at least one or several membrane

protein of Chalmydia (see col. 5, lines 32-42 and col. 12, lines 39-53), and teaches MOMP proteins are able to not only induce cross strain antibody binding, but also are produce neutralization of infectivity (see col. 8, lines 16-22).

Instant claim 20: wherein the nucleic acid coding sequence is obtained from Chlamydia pneumoniae (see col. 12, line 26).

Instant claim 21: wherein the nucleic acid coding sequence is obtained from Chlamydia trachomatis (see col. 12, line 25).

Instant claim 24: the nucleic acid is operatively coupled to a nucleic acid for expression of the membrane protein, the nucleic acid being a cytomegalovirus promoter (see col. 10, lines 47-63, col. 14, lines 24-38; col. 12, 31-53).

Instant claim 25: the vector is a plasmid vector (see col. 13, lines 61-63).

Instant claims 27-28: wherein the auxotrophic bacterium harbours a vector (see col. 4, lines 30-54 "a recombinant host system and related expression cassettes, vectors and transformed cells, ie live vaccine vector Salmonella typhimurium), formulated into a delivery vehicle.

Instant claim 26: Murdin et al teaches and suggests the formulation of vaccine vectors that can express one or several polypeptides and at least one additional Chlamydia antigen to include the nucleic acid that encodes MOMP (to include the nucleic acid that encodes MOMP (see col. 3, lines 60-67 and col. 4, lines 1-12(" Serovars of C. trachomatis are defined on the basis of antigenic variation in MOMP, but published C. pneumoniae MOMP gene sequences show no variation between several diverse isolates of the organism (refs. 34 to 36). The gene encoding a 76kDa antigen has been cloned from a single strain of C. pneumoniae and the sequence published (ref. 48)."), but differs from the instantly claimed invention by failing to show the nucleic acid sequence inserted into a plasmid vector in association with a cytomegalovirus promoter, which is harboured by the attenuated Salmonella typhimurium host cell.

8. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to formulate the attenuated Salmonella typhimurium vaccine vector that comprises a plasmid that encodes a Chlamydia membrane protein, to further encode and express at least one additional Chlamydia antigen (see Murdin et al col. 12, lines 32-48) , specifically MOMP protein under the control of a cytomegalovirus promoter as taught by Murdin et al because Murdin et al teaches, provides guidance and suggests the formulation of vaccine vectors that are able to express the encoded Chlamydia nucleic acid in the cells of a host for the induction of antibodies which will bind to Chlamydia because Chlamydia causes infection in mammals, to include humans (see col. 1, lines 15-16) .

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of obtaining the vaccine vector system which is able to be recombinantly express MOMP protein and to induce a neutralizing protective immune response directed against MOMP in the cells of a host, because Murdin et al teach the MOMP proteins have been successfully cloned and expressed and the MOMP proteins are immunogenic and induce neutralizing antibodies which assist in prevention of infection (see col. 8, lines 16-22) and Murdin et al teach, suggest and provide guidance for the incorporation of Chlamydial nucleic acids (at least one additional Chlamydial coding sequence) into the described vaccine vector systems (see claims and entire document), wherein the expressed Chalmydial proteins are able to induce a protective immune response (see col. 3, lines 62-67 and col. 4, lines 1-12). Murdin et al obviate the instantly claimed invention as now claimed.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp November 21, 2006

MARK NAVARRO
PRIMARY EXAMINER